

2102 '99 SEP -9 01:08

September 1, 1999

FDA Commissioner David Kessler
Dockets Branch
FDA
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket 96P0215

Dear FDA Commissioner David Kessler:

My name is Verlinda I. Bigby and wish to file a petition against the Wyeth-Ayerst maker of Norplant Birth Control Contraceptive.

In March 1995, I had the Norplant procedure performed while I was in the military at an U.S. Naval Hospital in Naples Italy. For the first 4 months I didn't have a menstrual cycle. This didn't concern me too much because I was told that I might experience missed cycles. Finally, when my cycle came on, I experienced severe heavy menstrual bleeding for one month, weight gain, severe headaches, dizziness and nausea. I didn't contact a doctor because my military medical benefits had expired. My next menstrual cycle came the following month, lasting only two days. Within the same month I had another menstrual cycle. The next menstruation came two months later, lasting two weeks. The menstrual cycles of one, two or three days to two weeks and no menstruation for two to three months lasted for 3 ½ years. I'm now on my 5th year still experiencing severe headaches (more frequently), dizziness, nausea along with eyes hurting, numbness and tingling feeling in my fingers with pain shooting to my upper arms, nervousness, feet swelling, and severe stomach cramps. My menstrual cycles comes every other month lasting anywhere from 1 – 14 days. Currently, my last menstruation was two months ago. All of these problems should not occur just to keep from getting pregnant. I'm in my last ½ year of Norplant's time-releasing, man made progesterin. I still don't have any medical coverage and is currently trying to save money to have the capsules removed in March 2000 or sooner. I'm putting myself at risk when I have the capsules removed – a life time scar and worse yet the possibility of sensory nerve damage in my arm. I will not have them reinserted.

96P-0215

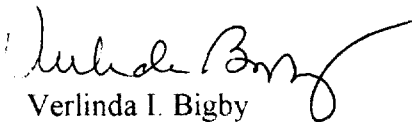
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I searched the internet about this product and found some shocking information. Had more information been made available to me prior to me having the Norplant inserted in March 1995 --- I would not have had the procedure done and would have just stayed on the pill. Now I have to suffer with weight gain, frequent severe headache, severe stomach cramps, dizziness, nausea, numbness and tingling feeling in my fingers with pain shooting to my upper arms, feet swelling, nervousness and putting myself at risk with any other side affects and a possibility of losing my life just as Miss Michelle Jordan. The Norplant has damaged not only me, but so many other women. This product must be withdrawn from the market before it causes any more damage or takes another life.

As I researched more, I found out that Norplant's manufacturer, Wyeth-Ayerst is aware of the link between their product and the adverse conditions it causes, and yet the product is still on the market. I would like to have my name added to the list of petitionars. A response would be greatly appreciated on the status of this matter.

Again, this product must be withdrawn from the market!

Sincerely,

A handwritten signature in black ink, appearing to read "Verlinda I. Bigby". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Verlinda I. Bigby

Lurlinda Bigby
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Hephzibah, GA 30815

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